

PCT

NOTIFICATION OF ELECTION

(PCT Rule 61.2)

From the INTERNATIONAL BUREAU

To:

Commissioner
US Department of Commerce
United States Patent and Trademark
Office, PCT
2011 South Clark Place Room
CP2/5C24
Arlington, VA 22202
ETATS-UNIS D'AMERIQUE

in its capacity as elected Office

Date of mailing:

22 February 2001 (22.02.01)

International application No.:

PCT/GB00/03011

Applicant's or agent's file reference:

P022524WO

International filing date:

04 August 2000 (04.08.00)

Priority date:

11 August 1999 (11.08.99)

Applicant:

BENTLEY, Jonathan, Mark et al

1. The designated Office is hereby notified of its election made:



in the demand filed with the International preliminary Examining Authority on:

06 December 2000 (06.12.00)



in a notice effecting later election filed with the International Bureau on:

2. The election ☒ was

was not

made before the expiration of 19 months from the priority date or, where Rule 32 applies, within the time limit under Rule 32.2(b).

The International Bureau of WIPO
34, chemin des Colombettes
1211 Geneva 20, Switzerland

Facsimile No.: (41-22) 740.14.35

Authorized officer:

J. Zahra

Telephone No.: (41-22) 338.83.38

PCT

INTERNATIONAL SEARCH REPORT

(PCT Article 18 and Rules 43 and 44)

Applicant's or agent's file reference P022524W0	FOR FURTHER ACTION see Notification of Transmittal of International Search Report (Form PCT/ISA/220) as well as, where applicable, item 5 below.	
International application No. PCT/GB 00/ 03011	International filing date (day/month/year) 04/08/2000	(Earliest) Priority Date (day/month/year) 11/08/1999
Applicant VERNALIS RESEARCH LIMITED		

This International Search Report has been prepared by this International Searching Authority and is transmitted to the applicant according to Article 18. A copy is being transmitted to the International Bureau.

This International Search Report consists of a total of 4 sheets.

☒ It is also accompanied by a copy of each prior art document cited in this report.

1. Basis of the report

- a. With regard to the **language**, the international search was carried out on the basis of the international application in the language in which it was filed, unless otherwise indicated under this item.

☐ the international search was carried out on the basis of a translation of the international application furnished to this Authority (Rule 23.1(b)).

- b. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international search was carried out on the basis of the sequence listing :

☐ contained in the international application in written form.

☐ filed together with the international application in computer readable form.

☐ furnished subsequently to this Authority in written form.

☐ furnished subsequently to this Authority in computer readable form.

☐ the statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.

☐ the statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished

2. ☐ **Certain claims were found unsearchable** (See Box I).

3. ☐ **Unity of invention is lacking** (see Box II).

4. With regard to the **title**,

☐ the text is approved as submitted by the applicant.

☒ the text has been established by this Authority to read as follows:

INDOLE DERIVATIVES, PROCESS FOR THEIR PREPARATION, PHARMACEUTICAL COMPOSITIONS CONTAINING THEM AND THEIR MEDICINAL APPLICATION

5. With regard to the **abstract**,

☒ the text is approved as submitted by the applicant.

☐ the text has been established, according to Rule 38.2(b), by this Authority as it appears in Box III. The applicant may, within one month from the date of mailing of this international search report, submit comments to this Authority.

6. The figure of the **drawings** to be published with the abstract is Figure No.

☐ as suggested by the applicant.

☐ because the applicant failed to suggest a figure.

☐ because this figure better characterizes the invention.

☐ None of the figures.

A. CLASSIFICATION OF SUBJECT MATTER

IPC 7 C07D209/80 C07D495/04 A61K31/403 A61K31/407 A61P25/28

According to International Patent Classification (IPC) or to both national classification and IPC

B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D

Documentation searched other than minimum documentation to the extent that such documents are included in the fields searched

Electronic data base consulted during the international search (name of data base and, where practical, search terms used)

EPO-Internal, CHEM ABS Data

C. DOCUMENTS CONSIDERED TO BE RELEVANT

Category °	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
Y	EP 0 655 440 A (HOFFMANN LA ROCHE) 31 May 1995 (1995-05-31) cited in the application claims 1-14,16-22 ---	1,4,5, 16-18, 25,28,29
Y	EP 0 657 426 A (HOFFMANN LA ROCHE) 14 June 1995 (1995-06-14) cited in the application claims ---	1,4,5, 16-18, 25,28,29
Y	US 3 329 571 A (L. M. RICE ET AL.) 4 July 1967 (1967-07-04) cited in the application column 1, line 13 - line 19; example 4 --- -/--	1,16-18, 28

☒ Further documents are listed in the continuation of box C.☒ Patent family members are listed in annex.

° Special categories of cited documents :

- "A" document defining the general state of the art which is not considered to be of particular relevance
- "E" earlier document but published on or after the international filing date
- "L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)
- "O" document referring to an oral disclosure, use, exhibition or other means
- "P" document published prior to the international filing date but later than the priority date claimed

- "T" later document published after the international filing date or priority date and not in conflict with the application but cited to understand the principle or theory underlying the invention
- "X" document of particular relevance; the claimed invention cannot be considered novel or cannot be considered to involve an inventive step when the document is taken alone
- "Y" document of particular relevance; the claimed invention cannot be considered to involve an inventive step when the document is combined with one or more other such documents, such combination being obvious to a person skilled in the art.
- "&" document member of the same patent family

Date of the actual completion of the international search

31 October 2000

Date of mailing of the international search report

10/11/2000

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

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Hass, C

C.(Continuation) DOCUMENTS CONSIDERED TO BE RELEVANT

Category *	Citation of document, with indication, where appropriate, of the relevant passages	Relevant to claim No.
A	DE 930 988 C (FARBENFABRIKEN BAYER AG) 28 July 1955 (1955-07-28) cited in the application examples 1,2,4,6,8-11 ---	1,28
A	US 3 142 678 A (L. M. RICE ET AL.) 28 July 1964 (1964-07-28) cited in the application column 1, line 23 - line 29; claims 1,3,8 ---	1,16,17, 28
A	US 2 541 211 A (J. W. CUSIC ET AL.) 13 February 1951 (1951-02-13) cited in the application examples 5,6 ---	1,28
A	US 2 687 414 A (J. W. CUSIC) 24 August 1954 (1954-08-24) cited in the application column 3, line 69 - line 72; examples 19,21 ---	1,16,28
A	EP 0 700 905 A (HOFFMANN LA ROCHE) 13 March 1996 (1996-03-13) cited in the application claims ---	1,16-18, 25,28,29
A	WO 98 30548 A (TSUKAMOTO SHIN ICHI ;KUBOTA HIDEKI (JP); MAENO KYOICHI (JP); SHIMA) 16 July 1998 (1998-07-16) cited in the application examples 27-32,46,35,36,47,49,50,51 -----	1,16,17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/B 00/03011

Patent document cited in search report		Publication date	Patent family member(s)	Publication date
EP 0655440	A	31-05-1995	AU 685841 B	29-01-1998
			AU 7583794 A	11-05-1995
			BR 9404203 A	04-07-1995
			CA 2132883 A	23-04-1995
			CN 1105988 A	02-08-1995
			CZ 9402604 A	18-10-1995
			FI 944969 A	23-04-1995
			HU 70848 A	28-11-1995
			IL 111314 A	17-08-1999
			JP 2638752 B	06-08-1997
			JP 7149723 A	13-06-1995
			NO 943999 A	24-04-1995
			NZ 264713 A	28-05-1996
			PL 305543 A	02-05-1995
			RU 2136662 C	10-09-1999
			US 5494928 A	27-02-1996
			ZA 9408094 A	24-04-1995
EP 0657426	A	14-06-1995	AT 168675 T	15-08-1998
			AU 680543 B	31-07-1997
			AU 7583894 A	11-05-1995
			BR 9404205 A	04-07-1995
			CA 2132887 A	23-04-1995
			CN 1105989 A, B	02-08-1995
			CZ 9402603 A	12-07-1995
			DE 59406489 D	27-08-1998
			DK 657426 T	26-04-1999
			ES 2120551 T	01-11-1998
			FI 944970 A	23-04-1995
			HU 70443 A, B	30-10-1995
			JP 2638751 B	06-08-1997
			JP 7149725 A	13-06-1995
			NO 944000 A	24-04-1995
			NZ 264711 A	26-07-1996
			PL 305544 A	02-05-1995
			RU 2128649 C	10-04-1999
			US 5646173 A	08-07-1997
			ZA 9408093 A	05-06-1995
US 3329571	A	04-07-1967	CH 470384 A	31-03-1969
			DE 1445416 A	23-01-1969
			DK 120748 B	12-07-1971
			DK 120541 B	14-06-1971
			DK 116282 B	29-12-1969
			NL 133522 C	
			NL 284655 A	
DE 930988	C		NONE	
US 3142678	A	28-07-1964	NONE	
US 2541211	A	13-02-1951	NONE	
US 2687414	A	24-08-1954	NONE	
EP 0700905	A	13-03-1996	AU 691310 B	14-05-1998
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			BR 9503630 A	28-05-1996

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/IB 00/03011


Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0700905 A		CA 2153937 A	13-02-1996
		CN 1131666 A,B	25-09-1996
		CZ 9502013 A	13-03-1996
		FI 953827 A	13-02-1996
		HU 72066 A	28-03-1996
		JP 2755560 B	20-05-1998
		JP 8059623 A	05-03-1996
		NO 953162 A	13-02-1996
		NZ 272731 A	25-09-1996
		PL 309974 A	19-02-1996
		TR 960124 A	21-06-1996
		US 5561150 A	01-10-1996
		ZA 9506553 A	12-02-1996
WO 9830548 A	16-07-1998	AU 5343298 A	03-08-1998

REC'D 20 NOV 2001

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INTERNATIONAL PRELIMINARY EXAMINATION REPORT

(PCT Article 36 and Rule 70)

Applicant's or agent's file reference P022524WO	FOR FURTHER ACTION	See Notification of Transmittal of International Preliminary Examination Report (Form PCT/IPEA/416)
International application No. PCT/GB00/03011	International filing date (day/month/year) 04/08/2000	Priority date (day/month/year) 11/08/1999
International Patent Classification (IPC) or national classification and IPC C07D209/80		
Applicant VERNALIS RESEARCH LIMITED et al.		
<p>1. This international preliminary examination report has been prepared by this International Preliminary Examining Authority and is transmitted to the applicant according to Article 36.</p> <p>2. This REPORT consists of a total of 8 sheets, including this cover sheet.</p> <p><input type="checkbox"/> This report is also accompanied by ANNEXES, i.e. sheets of the description, claims and/or drawings which have been amended and are the basis for this report and/or sheets containing rectifications made before this Authority (see Rule 70.16 and Section 607 of the Administrative Instructions under the PCT).</p> <p>These annexes consist of a total of sheets.</p>		
<p>3. This report contains indications relating to the following items:</p> <ul style="list-style-type: none">I <input checked="" type="checkbox"/> Basis of the reportII <input type="checkbox"/> PriorityIII <input checked="" type="checkbox"/> Non-establishment of opinion with regard to novelty, inventive step and industrial applicabilityIV <input type="checkbox"/> Lack of unity of inventionV <input checked="" type="checkbox"/> Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statementVI <input type="checkbox"/> Certain documents citedVII <input checked="" type="checkbox"/> Certain defects in the international applicationVIII <input type="checkbox"/> Certain observations on the international application		
Date of submission of the demand 06/12/2000	Date of completion of this report 15.11.2001	
Name and mailing address of the international preliminary examining authority:  European Patent Office D-80298 Munich Tel. +49 89 2399 - 0 Tx: 523656 epmu d Fax: +49 89 2399 - 4465	Authorized officer Uselli, A Telephone No. +49 89 2399 7366	



**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03011

I. Basis of the report

1. With regard to the **elements** of the international application (*Replacement sheets which have been furnished to the receiving Office in response to an invitation under Article 14 are referred to in this report as "originally filed" and are not annexed to this report since they do not contain amendments (Rules 70.16 and 70.17)*):

Description, pages:

1-56 as originally filed

Claims, No.:

1-30 as originally filed

2. With regard to the **language**, all the elements marked above were available or furnished to this Authority in the language in which the international application was filed, unless otherwise indicated under this item.

These elements were available or furnished to this Authority in the following language: , which is:

- ☐ the language of a translation furnished for the purposes of the international search (under Rule 23.1(b)).
- ☐ the language of publication of the international application (under Rule 48.3(b)).
- ☐ the language of a translation furnished for the purposes of international preliminary examination (under Rule 55.2 and/or 55.3).

3. With regard to any **nucleotide and/or amino acid sequence** disclosed in the international application, the international preliminary examination was carried out on the basis of the sequence listing:

- ☐ contained in the international application in written form.
- ☐ filed together with the international application in computer readable form.
- ☐ furnished subsequently to this Authority in written form.
- ☐ furnished subsequently to this Authority in computer readable form.
- ☐ The statement that the subsequently furnished written sequence listing does not go beyond the disclosure in the international application as filed has been furnished.
- ☐ The statement that the information recorded in computer readable form is identical to the written sequence listing has been furnished.

4. The amendments have resulted in the cancellation of:

- ☐ the description, pages:
- ☐ the claims, Nos.:
- ☐ the drawings, sheets:

5. ☐ This report has been established as if (some of) the amendments had not been made, since they have been considered to go beyond the disclosure as filed (Rule 70.2(c)):

INTERNATIONAL PRELIMINARY EXAMINATION REPORT

International application No. PCT/GB00/03011

(Any replacement sheet containing such amendments must be referred to under item 1 and annexed to this report.)

6. Additional observations, if necessary:

III. Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1. The questions whether the claimed invention appears to be novel, to involve an inventive step (to be non-obvious), or to be industrially applicable have not been examined in respect of:

- ☐ the entire international application.
- ☒ claims Nos. 25-28.

because:

- ☒ the said international application, or the said claims Nos. 25-27 (industrial applicability) relate to the following subject matter which does not require an international preliminary examination (*specify*):
see separate sheet
- ☒ the description, claims or drawings (*indicate particular elements below*) or said claims Nos. 28 are so unclear that no meaningful opinion could be formed (*specify*):
see separate sheet
- ☐ the claims, or said claims Nos. are so inadequately supported by the description that no meaningful opinion could be formed.
- ☐ no international search report has been established for the said claims Nos. .

2. A meaningful international preliminary examination cannot be carried out due to the failure of the nucleotide and/or amino acid sequence listing to comply with the standard provided for in Annex C of the Administrative Instructions:

- ☐ the written form has not been furnished or does not comply with the standard.
- ☐ the computer readable form has not been furnished or does not comply with the standard.

V. Reasoned statement under Article 35(2) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1. Statement

Novelty (N)	Yes: Claims 10,13,15,20-24,26
	No: Claims 1-9, 11,12,14,16-19,25,27,29,30
Inventive step (IS)	Yes: Claims
	No: Claims 1-27, 29,30
Industrial applicability (IA)	Yes: Claims 1-24, 29,30

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT**

International application No. PCT/GB00/03011

No: Claims

2. Citations and explanations
see separate sheet

VII. Certain defects in the international application

The following defects in the form or contents of the international application have been noted:
see separate sheet

Re Item III

Non-establishment of opinion with regard to novelty, inventive step and industrial applicability

1- Claims 25-27 relate to subject matter considered by this Authority to be covered by the provisions of Rule 67.1 (iv) PCT. Consequently, no opinion will be formulated with respect to the industrial applicability of the subject matter of these claims, cf. Article 34(4)(a)(i) PCT.

2- Claim 28 does not meet the requirements of Article 6 PCT in that the matter for which protection is sought is not clearly defined. The claim attempts to define the subject-matter in terms of the result to be achieved (i.e.: the preparation of the compounds of formula (I)) which merely amounts to a statement of the underlying problem. Accordingly, due to the lack of the technical features necessary for achieving this result a preliminary opinion in the sense of Art. 33(1) PCT cannot be given.

Re Item V

Reasoned statement under Rule 66.2(a)(ii) with regard to novelty, inventive step or industrial applicability; citations and explanations supporting such statement

1- In the present Opinion reference is made to the following documents:

d1: EP 0 655 440 A
d2: EP 0 657 426 A
d3: US 3 329 571 A
d4: DE 930 988 C
d5: US 3 142 678 A
d6: US 2 541 211 A
d7: US 2 687 414 A
d8: EP 0 700 905 A
d9: WO 98 30548 A

2- Novelty

2.1- D5 discloses penthienoindole derivatives represented by the general formula of

claim 1 which partially overlaps with the formula (I) of the present application. D5 discloses also a specific compound (example 4) encompassed by present formula (I). The compounds of d5 are pharmaceutical agents used as antidepressant, inhibitors of appetite, tranquillizers and for the treatment of CNS diseases (cf. column 1, lines 24-29).

Thus, in view of the disclosures of d5, the product claims including the compounds of d5 (claims 1-9, 11,12, 14) and the uses, methods and pharmaceutical compositions according to claims 16-19, 25,27,29,30 are not novel in the sense of Art. 33.2 PCT.

2.2- The compounds of the present application are novel vis-à-vis d1, d2, d8, d9 on account of the heterocyclic system (fused indole) which is not present in these documents and are novel vis-à-vis d4 on account of the R3 group.

The compounds of d3 differ from the compounds of the invention in that the ring fused to the indole moiety (corresponding to the present ring A) contains, at least, seven atoms.

The products of the examples 5-6 of d6 and 19, 21 of d7 are excluded from the scope of the present claims for the effect of the proviso of claim 1.

3- Inventive step

3.1- D3 discloses tricyclic compounds acting on the central nervous system and useful as antidepressant, inhibitors of appetite, and tranquillizers. This document is regarded as the closest state of the art. The technical problem can be considered the provision of further agents for the treatment of the diseases defined in claims 17-18.

As already indicated, the compounds of d3 merely differ from the compounds of the invention for the size of the ring fused to the indole moiety. For instance, the compound of Example 4 of d3 differs from the compounds of present formula (I) only for the presence of an additional CH₂ group.

It appears that, due to the similar or identical activity to the compounds of d3, the skilled person starting from the teaching of this document would arrive to the compounds of the invention without any inventive activity.

Thus, in the absence of unexpected properties vis-à-vis the compounds of d3, do not satisfy the requirements of Art. 33(3) PCT.

3.2- Additionally, it is also observed that the possible generalisations of the activity

shown for specific compounds should extend only to those variants being obvious modifications and equivalents of the compounds tested. In the present case, the results of the tests given on page 19-20 of the description, concern almost always compounds where R4-R7 are halogen or small alkoxy groups. It appears that starting from these data there is no basis for assuming that those compounds substituted by radicals such as aryloxy or carbo-aryloxy maintain the same activity. In general, the non-limitative definitions used in the claims such as aryl, alkyl and prodrugs (cf. claim 1) have the effect of extending the scope of the claims to an undefined class of compounds for which the claimed activity can never be convincingly shown. It is remembered that only those compounds which represent a solution of the technical problem could be considered inventive

4- Industrial applicability

For the assessment of the present claims 25-27 on the question whether they are industrially applicable, no unified criteria exist in the PCT Contracting States. The patentability can also be dependent upon the formulation of the claims. The EPO, for example, does not recognize as industrially applicable the subject-matter of claims to the use of a compound in medical treatment, but may allow, however, claims to a known compound for first use in medical treatment and the use of such a compound for the manufacture of a medicament for a new medical treatment.

Re Item VII

Certain defects in the international application

1- The statement in the description on page 6, 2° paragraph, concerning the possibility of the groups R1-R7 to be substituted, implies that the subject-matter for which protection is sought may be different to that defined by the claims, thereby resulting in lack of clarity (Article 6 PCT) when used to interpret them (see also the PCT Guidelines, III-4.3a).

2- To meet the requirements of Rule 5.1(a)(ii) PCT, the relevant background art disclosed in all the documents cited in the International Search Report should be identified and briefly discussed.

**INTERNATIONAL PRELIMINARY
EXAMINATION REPORT - SEPARATE SHEET**

International application No. PCT/GB00/03011

3- The sentence "It will be...invention" (page 17, lines 23-24) is considered irrelevant and thus superfluous, cf. Rule 9.1 (iv) PCT.

INTERNATIONAL SEARCH REPORT

Inter Application No

PCT/GB 00/03011

CLASSIFICATION OF SUBJECT MATTER

C 7 C07D209/80 C07D495/04 A61K31/403 A61K31/407 A61P25/28

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B. FIELDS SEARCHED

Minimum documentation searched (classification system followed by classification symbols)

IPC 7 C07D

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"L" document which may throw doubts on priority claim(s) or which is cited to establish the publication date of another citation or other special reason (as specified)

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"&" document member of the same patent family

Date of the actual completion of the international search

31 October 2000

Date of mailing of the international search report

10/11/2000

Name and mailing address of the ISA

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Fax: (+31-70) 340-3016

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Hass, C

INTERNATIONAL SEARCH REPORT

Interr Application No

PCT/GB 00/03011

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A	US 2 687 414 A (J. W. CUSIC) 24 August 1954 (1954-08-24) cited in the application column 3, line 69 - line 72; examples 19,21 ---	1,16,28
A	EP 0 700 905 A (HOFFMANN LA ROCHE) 13 March 1996 (1996-03-13) cited in the application claims ---	1,16-18, 25,28,29
A	WO 98 30548 A (TSUKAMOTO SHIN ICHI ;KUBOTA HIDEKI (JP); MAENO KYOICHI (JP); SHIMA) 16 July 1998 (1998-07-16) cited in the application examples 27-32,46,35,36,47,49,50,51 -----	1,16,17

INTERNATIONAL SEARCH REPORT

Information on patent family members

International Application No

PCT/GB 00/03011

Patent document cited in search report	Publication date	Patent family member(s)	Publication date
EP 0700905 A		CA 2153937 A	13-02-1996
		CN 1131666 A,B	25-09-1996
		CZ 9502013 A	13-03-1996
		FI 953827 A	13-02-1996
		HU 72066 A	28-03-1996
		JP 2755560 B	20-05-1998
		JP 8059623 A	05-03-1996
		NO 953162 A	13-02-1996
		NZ 272731 A	25-09-1996
		PL 309974 A	19-02-1996
		TR 960124 A	21-06-1996
		US 5561150 A	01-10-1996
		ZA 9506553 A	12-02-1996
WO 9830548 A	16-07-1998	AU 5343298 A	03-08-1998

INTERNATIONAL SEARCH REPORT

Information on patent family members

Interr Application No

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